CollaFirm LLC
Princeton Park Plaza
7 Deer Park Drive, Suite M-7
Monmouth Junction, NJ 08852

APR 2 1 2013

K120250

510(k) SUMMARY

1. **Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.**

   CollaFirm LLC
   7 Deer Park Drive, Suite M-7
   Monmouth Junction, New Jersey 08852

   Telephone No.: 732-823-1051
   Facsimile No.:

   Contact Person: Surendra Batra Ph.D.
   E-Mail: surendra@collafirm.com

   Date Prepared: April 17, 2013

2. **Name of Device and Name/Address of Sponsor**

   CollaFirma Collagen Wound Dressing

   CollaFirm LLC
   7 Deer Park Drive, Suite M-7
   Monmouth Junction, New Jersey 08852

3. **Common or Usual Name:** Collagen Wound Dressing

4. **Classification:** Dressing, Wound, Collagen
   Regulatory Class: Unclassified
   Product Code: KGN

5. **Description:** CollaFirm Collagen Wound Dressing, a highly purified porcine Type I, collagen wound dressing which, when applied to a wound surface, absorbs wound fluid and maintains a moist wound environment in the management of wound healing. The CollaFirm Collagen Wound Dressing is provided in a patient ready, one (1) gram, envelop.

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6. **Predicate Devices**

   - Medifil Particles K910944 , BioCore Medical Technologies,Inc.
   - CollaTek Power K012990 BioCore Medical Technologies,Inc.

7. **Intended Use/Indication for Use:** CollaFirm Collagen Wound Dressing is indicated for the management of full and partial thickness wounds including; pressure ulcers, diabetic ulcers, ulcers caused by mixed vascular origin, venous ulcers, donor and graft sites, abrasions, traumatic wounds healing by secondary intention, dehisced surgical wounds, first and second degree burns.
   For Prescription use

8. **Amino Acid Analysis**: Amino Acid Analysis for CollaFirm collagen was performed by HPLC and was compared with Medfil II collagen particles. The amino acid composition (18 amino acids each) of CollaFirm collagen and predicate device Medfil II is quite similar on comparison.

9. **Technological Characteristics:** CollaFirm Collagen Wound Dressing is highly purified porcine collagen which absorbs wound fluid, maintains a moist wound environment and is equivalent to predicate products currently in commercial distribution.

   This particular formulation does not affect the intended use or alter the fundamental scientific technology of the device.

10. **Substantial Equivalence:** The CollaFirm Collagen Wound Dressing is as safe and effective as the predicate devices referenced herein. CollaFirm Collagen Wound Dressing has the same intended uses, technological characteristics, and basic principles of operation as the aforementioned predicate devices and raises no new issues of safety or effectiveness. CollaFirm Collagen Wound Dressing is substantially equivalent to the predicate devices referenced.

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11. **Non-Clinical Performance Data:** The CollaFirm Collagen Wound Dressing has been evaluated in accordance with Part 10-993 of the International Standard Organization (ISO). Standard tests which include:

    - Agar Overlay (direct contact) Cytotoxicity testing indicated a grade 0 cytotoxic grade.
    - ISO Intracutaneous reactivity (Irritation) testing indicates a non-irritant.
    - ISO Guinea Pig Maximization Sensitization Test Report indicates the product is a non-sensitizer.
    - Stability has been demonstrated over a three (3) month period and Room Temperature and accelerated conditions and was found to maintain the products attributes and characteristics.
    - USP Sterility testing has indicated that the product is sterile.
    - LAL Chromogenicity testing indicates the product is non-pyrogenic.
    - CollaFirm Collagen Wound Dressing has not been studied in a clinical setting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

CollaFirm, LLC
% Surendra Batra, Ph.D.
7 Deer Park Drive, Suite M-7
Monmouth, New Jersey 08852

April 21, 2013

Re: K120250
Trade/Device Name: CollaFirma Collagen Wound Dressing
Regulatory Class: Unclassified
Product Code: KGN
Dated: April 08, 2013
Received: April 10, 2013

Dear Dr. Batra:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CollaFirm LLC
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CollaFirm Collagen Wound Dressing
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K120250/S002

Indications for Use

510(k) Number: K120250

Device Name: CollaFirm Collagen Wound Dressing

Indications for Prescription (Rx) Use:

CollaFirm Collagen Wound Dressing is indicated for the management of full and partial thickness wounds including; pressure ulcers, diabetic ulcers, ulcers caused by mixed vascular origin, venous ulcers, donor and graft sites, abrasions, traumatic wounds healing by secondary intention, dehisced surgical wounds, first and second degree burns.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___ ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K120250